REMARKS

Favorable consideration and allowance are respectfully requested for claims 17 and 38 in view of the following remarks.

The Examiner is thanked for the courtesies extended during the personal interview held August 1, 2005, the substance of which is reflected herein.

The rejection of claim 17 under 35 U.S.C. § 102(e) as anticipated by Mauskop (U.S. Patent 5,914,129) is respectfully traversed.

Claim 17 of the present application covers a **compound** formed from tramadol hydrochloride and diclofenac sodium. Mauskop, on the other hand, suggests the possibility of a **mixture** of tramadol and diclofenac. This is a significant difference as the release rate of the **compound** of tramadol hydrochloride and diclofenac sodium is significantly different from the release rate of tramadol hydrochloride and diclofenac sodium in the form of a **mixture**.

Claim 17 recites "a compound of tramadol hydrochloride and diclofenac sodium." The claim then describes that "said compound" is formed in situ and that the compound has a water solubility of ≤100 mg/ml. Thus, it is clear that the claim is directed to a compound of tramadol hydrochloride and diclofenac sodium and not simply a mixture of these two ingredients.

As evidence of the difference between compounds of diclofenac sodium and tramadol hydrochloride, a declaration of Dr. Iris Ziegler, dated September 23, 2005 is provided as Appendix A to this Reply. As explained in Dr. Ziegler's declaration, tablets of a mixture of tramadol hydrochloride and diclofenac sodium were prepared in accordance with the teachings of Mauskop (see Test I). Tablets formed of a compound of tramadol hydrochloride and diclofenac sodium were also formed by the methods described in the present patent application (see Test II). The release profiles of tramadol and diclofenac from the tablets of Test I and Test II were then determined.

The graph appearing at the bottom of page 4 of the declaration shows a comparison of the release profiles of tramadol and diclofenac from the tablets of Test I and Test II in simulated intestinal fluid. The squares and associated curves in the graph, as well as the accompanying explanation on page 5, show that tramadol and diclofenac were both fully released from the tablets of Test I within 15 minutes. The triangles and associated curves in the graph show a significantly extended release profile for tramadol and diclofenac as claimed. The data shown in the graph reveals that the tramadol and diclofenac were not fully released at even 600 minutes. In fact, at 600 minutes the release of diclofenac had only reached about 85%. This evidence shows that the release profile of a compound of tramadol and diclofenac as presently claimed is significantly different from that of a mixture of tramadol and diclofenac as taught by Mauskop.

Accordingly, a simple mixture or composition that contains diclofenac sodium and tramadol hydrochloride is not the same as the invention set forth in claim 17. A reference which merely teaches a mixture of diclofenac sodium and tramadol hydrochloride does not amount to a teaching of a compound of diclofenac sodium and tramadol hydrochloride as presently claimed, and therefore such a reference cannot anticipate claim 17. Reconsideration and withdrawal of this rejection are respectfully requested.

The rejection of claim 38 under 35 U.S.C. § 103(a) as unpatentable over Mauskop (U.S. Patent 5,914,129) is respectfully traversed. Among other things, claim 38 requires repeating mixing and moistening steps and also requires formulating the mixture under an energy input. Neither of these steps are taught or suggested by the Mauskop reference. The Office Action asserts that repeating the mixing and moistening steps is an obvious variant of the method taught in the reference. To the contrary, the reference provides no teaching or suggestion that it would be of any use or benefit to try to repeat the mixing and

moistening steps. Accordingly, one of skill in the art would not be encouraged to try to modify the methods of Mauskop so as to arrive at a method that includes repeating the mixing and moistening steps. Even assuming, arguendo, that one of skill in the art contemplated repeating the mixing the moistening steps, this person would have no reason to believe that the additional steps would provide any additional benefit. The person of skill in the art would certainly understand, however, that the additional steps would take additional time and thereby increase the production costs. The Office Action asserts that specific cost amounts for the increase costs of adding steps to the method of Mauskop were not provided. There is no requirement in this instance that specific cost amounts be provided. In fact, the specific costs would vary from manufacturer to manufacturer, perhaps even from day to day within a single plant of a single manufacturer. The one constant is that whenever an extra step is added to a manufacturing process such as that presently contemplated by the claim, the time required to perform the steps of the process will lengthen and the overall costs of production will increase. The importance of minimizing production costs for industrial manufacturing is not to be underestimated and the Patent Office is ill suited to subjectively judge the merit of an invention on the basis of whether a cost increase is sufficiently significant to cause one of skill in the art to avoid such steps. The mere fact that there is any increase in costs is adequate to cause one of skill in the art to be averse to the additional steps. This is especially true in the present instance where the person of skill in the art would have no reason to even suspect that repeating the mixing and moistening steps would be of any added benefit. Thus, the specific costs are irrelevant and the fact that there is any increase in costs is sufficient to deter one of skill in the art from performing the additional steps. Accordingly, Mauskop provides no suggestion or motivation to one of skill in the art to try to modify its teachings so as to arrive at the presently claimed invention.

The Office Action of June 15, 2004 admits that the Mauskop reference does not specifically disclose formulating the mixture under energy input. That Office Action also asserts that compressing or granulating as taught in Remington's Pharmaceutical Sciences amounts to an energy input. However, the claim does not simply require an energy input, rather, the claim requires "formulating the mixture under an energy input." The more recent Office Action asserts that the process of mixing involves energy input, and appears to contradict the earlier Office Action in this respect.

The claim recites "mixing tramadol hydrochloride and diclofenac sodium to form a mixture" and then as a separate step, "repeating the above mixing and moistening steps and formulating the mixture under an energy input." If the claim is read as suggested by the Office Action to interpret the mixing to amount to the energy input, the reading gives essentially no meaning to the language "formulating the mixture under an energy input." Claims are not interpreted so as to render the language therein superfluous or redundant.

Because the reference does not teach or suggest every element of the claim and because one of skill in the art would have no motivation to try modify the reference so as to arrive at the claimed invention, the reference does not render claim 38 obvious. Accordingly, reconsideration and withdrawal of the obviousness rejection are respectfully requested.

Claim 17 was provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 11 of co-pending Application no. 10/016,130. Claim 17 of the present application is patentably distinct from the claims of co-pending Application no. 10/016,130. As explained above, a basic requirement of claim 17 is that tramadol hydrochloride and diclofenac sodium are formulated into a compound. In contrast thereto, a basic requirement of the embodiments of Application no. 10/016,130 is that tramadol and diclofenac and/or their respective physiologically compatible salts

are present in separate subunits which are each separately formulated. Further, co-pending Application no. 10/016,130 teaches a separation layer between the two separately formulated sub-units in order to avoid any contact between the two active substances. Because the co-pending application requires separate formation of the two active substances, and the present application requires formation of the two active substances together into a compound, the claims are patentably distinct.

Accordingly, the subject matter of the present claims is not obvious in view of the claims of the earlier application and withdrawal of the provisional obviousness-type double-patenting rejection is respectfully requested.

CONCLUSION

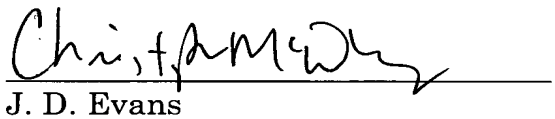
In view of the foregoing, the application is respectfully submitted to be in condition for allowance and prompt favorable action thereon is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #029310.50932).

Respectfully submitted,

October 13, 2005



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